UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	14

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/508,635	Ballevre
Examiner	**Art Unit**
David Lukton	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Feb 16, 2001*

2a) [ ] This action is **FINAL.** 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *11-29* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) [ ] Claim(s) _____ is/are allowed.

6) [ ] Claim(s) _____ is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [X] Claims *11-29* are subject to restriction and/or election requirem

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) [ ] Notice of References Cited (PTO-892)

16) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

18) [ ] Interview Summary (PTO-413) Paper No(s) _____

19) [ ] Notice of Informal Patent Application (PTO-152)

20) [ ] Other

Pursuant to the directives of paper No. 13 (filed 2/16/01), claims 1-10 have been cancelled, and claims 11-29 added. Claims 11-29 are pending.

A new restriction is imposed, even though it is technically subsequent to the first action on the merits. However, the originally presented claims were all drawn to a "use". As applicants' representative is well aware, a "use" (per se) is not a proper statutory class of invention. Accordingly, it was impossible at the time of the (so-called) "first action on the merits" to determine what applicants were attempting to claim. Accordingly, the reality is that no examination has yet been undertaken, other than to point out the impropriety of "use" claims. No search has yet been undertaken, and the IDS has not yet been considered. For all practical purposes, no "first action on the merits" has yet been undertaken. Not only have applicants now submitted an **entirely new class of invention** (i.e., a "method of use, versus a "use" *per se*), but in addition, applicants are now claiming an invention which is substantively different from what was previously claimed, and equally important, applicants are now claiming an invention which is substantively different from what was previously elected. Previously, applicants elected Group I, which was drawn to a "use" of dietary protein to increase protein synthesis. Now, applicants are claiming a method for promoting the growth or recovery of an organ. However, these are not the same. The examiner nevertheless will bear with applicants' decision to change both the class of the invention, and the substance of the invention. But given this, imposing a new restriction

at this point is fully justified.

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A restriction is imposed, as set forth below. First, however, the following subgenera are defined (G1 and G2 are the same as before):

G1: this subgenus is limited to a method of using a dietary protein to increase protein concentration and synthesis in the intestine, the duodenum, or the jejunum

G2: this subgenus is limited to a method of using a dietary protein to maintain muscle protein synthesis, or for the treatment of muscular atrophy.

G3: this subgenus is limited to a method of using a dietary protein to increase protein concentration and synthesis.

G4: this subgenus is limited to a method of treating muscular atrophy.

G5: this subgenus is limited to a method of enhancing the recovery of damaged organ *in vitro*.

G6: This subgenus is limited to a method for promoting the growth or recovery of a specific organ in a mammal, or a method of enhancing the recovery of damaged organ in a mammal, wherein there are no limitations on the mechanism by which these objectives are achieved.

*

Restriction to one of the following inventions is required under 35 U.S.C. §121 (the numbering begins with "III" to avoid conflict with the first restriction)

III. Claims 11-13, 15-29, drawn to a method of promoting the growth or recovery of a specific organ in a mammal, or a method of enhancing the recovery of damaged organ in a mammal, wherein G6 is included, but G3, G4, and G5 are excluded.

IV. Claims 14 and 27-29, drawn (possibly in the future) to a method of increasing protein synthesis, or to a method of enhancing the recovery of damaged organ *in vitro*.

Claims 27-29 are common to both groups.

The claimed inventions are distinct.

The issue here is largely one of inherency, and the possibility that, at some point in the future, applicants will add a claim such as the following:

> *A method of increasing protein concentration and synthesis in a specific organ of a mammal comprising administering a dietary protein to said mammal.*

There is, in fact, nothing to preclude applicants from submitting this very claim, or one like it, in response to this Office action. The primary purpose of this Office action, however, is to make the point that if Group III is elected in response to this Office action, the "window of opportunity" for adding such a claim will close. It is the contention of the examiner that a claim drawn to a method of increasing protein concentration and/or synthesis is distinct from a method of promoting growth or recovery of an organ. A given reference could in fact teach the use of proteins or peptides to promote growth or recovery of an organ without specifically identifying increased protein synthesis as the mechanism. In such

species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The first "specie" is a specific "organ", such as the duodenum. The second "specie" is one of the following: (a) an unhydrolyzed dietary protein, (b) a protein hydrolyzate, or (c) "free amino acids". [Applicants' previously elected the protein hydrolyzate; this election should be re-affirmed, if consistent with intentions, in order to avoid any misunderstanding].

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800

US 095086350FP1

Creation date: 09-22-2003
Indexing Officer: HGOITOM - HANNA GOITOM
Team: OIPEBackFileIndexing
Dossier: 09508635

Legal Date: 05-10-2001

No.	Doccode	Number of pages
1	EXIN	3

Total number of pages: 3

Remarks:

Order of re-scan issued on .....